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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,475		Olav K. Lyngberg	110.00810101	7111

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EXAMINER

CHEU, CHANGHWA J

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 09/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/647,475

**Applicant(s)**

LYNGBERG ET AL.

**Examiner**

Jacob Cheu

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24,48 and 100-110 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24,48 and 100-110 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Applicant's amendment filed on 7/9/2004 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claim 25-47, 49-99 are cancelled.
2. Claims 1-4, 6-8, 11-12, 14, 16, 18, 22, 109 and 110 are amended.
3. Currently, claims 1-24, 48, 100-110 are pending for examination.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 1-24, 48, 100-110 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, the phrase "composition biological device comprising a biostructure comprising at least one biological material as an integral imbedded component thereof" is vague and indefinite. It is not clear where this biological material is imbedded, e.g. in the non-porous material, or other material. Similarly, claims 2, 3, 4, 11, 12, 14, 16, 18, 22, 109 and 110 suffer the same problem.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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1. Claims 1-2, 6-13, 15-24, 48, 100, 109-110 are rejected under 35 U.S.C. 102(b) as being anticipated by Thiagarajan et al. (European Federation of Biotechnology, 1995, page 304-312).

Thiagarajan et al. teach a composite biological device by integrally imbedding, i.e. permanently immobilized, viable bacterial on biofilm, i.e. acrylic vinyl acetate, with a polyester nonporous polymer sheet for measuring oxygen consumption when the biostructure is metabolically activated by rehydration (See Introduction; Materials and Method) The device can detect oxygen consumption which reflects metabolic activity of the viable genetically recombinant *E coli* strain ZK211 bacteria (See Figure 6-8). The biostructure is desiccation tolerant since the process involving dryness. (page 308, first paragraph) Thiagarajan et al. teach using oxygen probes to measure the alternation of oxygen level when culturing the biostructure with starvation or growth media (See Introduction). The measurement of oxygen by oxygen-probe inherently involves electrodes, transmitter, detector and signal response (See Figure 1, 6-8). Furthermore, Thiagarajan et al. teach that the thickness of the cell layer is approximately 70 microns which is less than 500 microns within the range of the instant invention (See page 306, first paragraph). Furthermore, the device taught by Thiagarajan et al. comprising a porous sealant layer that does not include biological material, i.e. silicone rubber sealant (See page 308, first paragraph).

#### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 3 and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thiagarajan et al. in view of Inouye et al. (EP 0314338).

Thiagarajan et al. reference has been discussed but is silent in teaching use of nonporous material, e.g. non-water permeability, as a channel or well for containing sample. Inouye et al. teach using microplate of latex, polystyrene or glass immobilized antibody holding samples for immunoassay (See claim 10). The microplate is nonporous, i.e. not water permeable. It would have been obvious to one ordinary skilled in the art at the time when invention was made to have provided Thiagarajan et al. with the microplate of latex as a holding means for the tested sample because the materials are nonporous suitable for containing sample, and it merely involves routine practice in the art to use different materials, such as glass, aluminum, polystyrene, or latex for wells, channels or reservoirs containing tested samples.

5. Claims 103-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thiagarajan et al. in view of Mulchandani et al. (Analytical Chem. 1998 Vol. 70: 4140).

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Thiagarajan et al. reference has been discussed but is silent in teaching applying the biostructure to detect an analyte in a test sample. Mulchandani et al. teach a microbial biosensor in detecting environmental pollutants, such as pesticides or insecticides or other chemical warfare agents (See Introduction). Mulchandani et al. teach a quick, simple, cost-effective environmental monitoring technology by immobilizing E Coli on a polymer substrate and detect changes of the enzymatic activity in E Coli in the presence of analytes (See Materials and Methods; page 4142, page 4141). The measurement apparatus involves electrodes, transmitters and signal responses (See Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have motivated Thiagrajan et al. to apply the instant biostructure to detect environmental chemicals as taught by Mulchandani et al. because it is an analogous art, i.e. immobilizing whole E Coli on polymers, with a similar goal, i.e. cost-effective and efficient environmental monitoring.

6. Claims 1-20, 22, 48, 109-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cantwell et al. (EP 0288203) in view of Inouye et al. (EP 0314338).

Cantwell et al. teach a composite biological composition comprising permanently imbedding cells on the nonporous polymers, e.g. latex. (See abstract; page 3- page 4) The cells are selected from bacteria and fungi, and can be metabolically activated by rehydration in a well, e.g. bioreactor (See page 6, Example 1). Bacteria containing certain detectable enzyme, such as catalase, oxygenase, dehalogenase, could be inherently genetically manipulated into different strain. (page 6, example 1; claim 1-8) The cells and each polymer were used at a concentration of 10% w/v. (page 6-8) The immobilizing cells on the latex is by several forces, including cross-linkage method. (page 2, line 25-30) The composition is inherently desiccation tolerant because the composition is in a colloidally stable condition when mixing with cells, and using polyvinylidene chloride polymer additives (page 4, line 45-57). Cantwell et al. teach measuring enzymatic

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activities by spectrophotometer which inherently involves signal response, wires, transmitter and detector (See page 7, first paragraph).

However, Cantell et al. do not specifically disclose the materials of the bioreactor, e.g. nonporous latex. Inouye et al. teach using microplate of latex, polystyrene or glass immobilized antibody holding samples for immunoassay (See claim 10). The microplate is nonporous, i.e. not water permeable. It would have been obvious to one ordinary skilled in the art at the time when invention was made to have provided Cantwell et al. with a non-water permeable nonporous material such as nonporous latex because it is not water permeable suitable for the detecting purpose and it merely involves routine practice in the art to use different materials, such as glass, aluminum, polystyrene, or latex for wells, channels or reservoirs holding tested samples.

### ***Response to Applicant's Arguments***

7. Claims 1-3, 6-22, 48, 100-108 are rejected under 35 U.S.C. 102(a) as anticipated by Nova et al. are withdrawn.
8. Applicant's arguments with respect to claims 1-2, 6-7, 9-13, 15, 18, 22, 48, 100, 109-110 under 35 USC 102(b) as anticipated by Thiagarajan et al. are maintained.
9. Applicant's arguments with respect to claims 1, 4-10, 14-15, 18-20, 100-110 as anticipated by Cantwell et al. under 35 USC 102 (b) have been considered but are moot in view of the new ground(s) of 103 (a) rejection set forth in this Office Action.

### ***Issue of "Metabolically Active"***

10. Applicant's newly submitted Remarks/Arguments define the term of "metabolically active" as (1) gene expression; (2) protein synthesis; (3) ATP production; (4) production of reducing equivalents such as NADH, NADPH and FADH, (5) DNA or RAN synthesis and (6) ability to be recovered as viable cells, as opposed to cells merely catalyzed enzymatic activities

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(See page 2, first paragraph). Applicant argues that Thiagarajan et al. reference merely teaches measuring oxygen consumption which is not within the scope of the “metabolically active” defined by this list.

Applicant’s arguments have been considered but are not persuasive. Examiner would like to remind applicant that applicant *admits* that the biological materials are capable of exerting various biological responses, including changes in production of an enzyme metabolites, changes in production of oxygen (See that page 13, line 1-15). Particularly, such responses are “typically produced upon contact with an analyte in a sample being analyzed.” (page 13, line 10-11) The biological responses, such as alternation in oxygen consumption or enzymatic activities, are typical “metabolic active” viable cells. Furthermore, it is well-known and commonly accepted in scientific community that these changes are used to measure metabolic activity of viable cells (See Thiagarajan et al. reference).

#### *Thiagarajan et al. Reference*

11. Applicant argues that Thiagarajan et al. reference use aluminum plugs, e.g. not a nonporous polymer as used in the instant invention. In addition, Thiagarajan et al. do not teach a method to determine the presence of an analyte, or a method wherein a biological material produces a response and emits a signal upon contact an analyte. Applicant’s arguments have been considered but are not persuasive.

First, Examiner broadly interprets the claims in light of the Thiagarajan et al. reference where a non-porous latex material, i.e. polyester, was incorporated in the biostructure (See Materials and Method of Thiagarajan et al.). Second, in light of the new 103 (a) rejections set forth in this Office Action, Examiner provides Mulchandani et al. reference showing using immobilizing E Coli in detecting environmental analyte in a tested sample. The measurement of enzymatic changes in response to the presence of the analytes involves electrodes, transmitter, detector and signal response (See Figure 1 in Mulchanandani reference).



*Cantwell et al. Reference*

12. Applicant argues that Cantwell reference (1) does not teach a non-porous material or that the biological material that is metabolically active; (2) a method of utilizing such device.

Applicant's arguments have been considered but are not persuasive. First, Examiner had established in this Office Action that applicant admits that the measurement of enzymatic activity, such as oxygenase taught by Cantwell is "metabolically active." Second, in light of new ground of 103 (a) rejection, Examiner provides a new Inouye et al. reference in combination of Cantwell et al. reference showing that using the nonporous materials, such as wells, channels, or reservoirs, to contain tested samples are within routine skilled in the art. Therefore, in Examiner's opinion, the instant feature of "nonporous" materials, in either Thiagarajan or Cantwell reference, merely involves ordinary skilled in the art not entitled for patentability.

*Conclusion*

13. No claim is allowed.

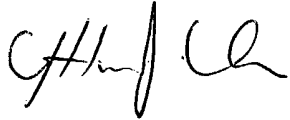
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

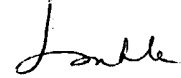
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu  
Examiner  
Art Unit 1641



September 9, 2004



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